

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION**

CINDY BURTON,	§	
Plaintiff,	§	
	§	
V.	§	CIVIL ACTION NO.
	§	3:99-CV-0305-G
WYETH-AYERST LABORATORIES	§	
DIVISION OF AMERICAN HOME	§	ECF
PRODUCTS CORPORATION, ET	§	
AL.,	§	
Defendants.	§	

**DEFENDANT WYETH'S REPLY BRIEF IN SUPPORT OF
MOTION FOR PARTIAL SUMMARY JUDGMENT**

TABLE OF CONTENTS

	Page
Plaintiff Failed To Raise A Material Issue Of Fact On Causation	1
I. Summary of the Argument.....	1
II. Plaintiff Fails to Raise a Material Issue of Fact on Causation.....	3
A. There is No Epidemiologic Evidence Showing an Association Between Diet Drugs and Plaintiff’s Condition.....	3
1. IPPHS	5
2. SNAPH	6
B. Plaintiff Claims Exercise-Induced PAH	6
1. Dr. Poon.....	7
2. Dr. Palevsky	8
3. Dr. Channick	9
C. The “Consensus Definition” of PPH Does Not Supply Causation Evidence.....	10
1. The Settlement Agreement	10
a. The Settlement Definition Expressly was	10
Broader Than the Studies.....	10
b. Plaintiff Rejected Any Benefits of the Broader Settlement Agreement Definition.....	12
2. The Diet Drug MDL Court’s Actions Are Not Evidence of Causation	13
3. Plaintiff’s Misstatements and Inflammatory, Irrelevant Accusations Are Not Evidence of Causation.....	14
a. Defense Experts Dispute Causation	14
b. “No Literature”	15

c.	Conclusory Opinion.....	16
d.	Injection of Liability Arguments	17
D.	Dr. Palevsky’s “Sham” Declaration and Conclusory Assertions Should Be Disregarded or Stricken	17
1.	Dr. Palevsky’s Contradictory Testimony.	18
a.	Progression of Exercise-Induced Pulmonary Hypertension	18
b.	Causation.....	21
2.	Conclusory Statements on Causation	22
F.	Plaintiff’s Unsupported Arguments Are Not Summary Judgment Evidence	23
	Conclusion.....	24
	Certificate of Service.....	25

TABLE OF AUTHORITIES

Case	Page
<i>Branch v. Fid. & Cas. Co. of New York</i> , 783 F.2d 1289 (5 th Cir. 1986).....	12
<i>Brown v. Am. Home Prods. Corp., In re: Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig.</i> , 2000 WL 1222042 (E.D. Pa. Aug. 28, 2000) (PTO 1415).....	11
<i>Calbillo v. Cavender Oldsmobile, Inc.</i> , 288 F.3d 721 (5 th Cir. 2002).....	23
<i>Campanello v. Anthony & Sylvan Pools Corp.</i> , No. Civ. A. 3:03-CV-1884-G, 2004 WL 2049313 (N.D. Tex. Sept. 14, 2004).....	18
<i>Clark v. America's Favorite Chicken Co.</i> , 110 F.3d 295 (5 th Cir. 1997).....	17, 18, 21, 22
<i>Copeland v. Wasserstein, Perella & Co., Inc.</i> , 278 F.3d 472 (5 th Cir. 2002).....	18
<i>Doe v. Dallas Indep. Sch. Dist.</i> , 220 F.3d 380 (5 th Cir. 2000).....	18
<i>Exxon Corp. v. Makofski</i> , 116 S.W.3d 176 (Tex. App. – Houston [14 th Dist.] 2003, pet. denied).....	5
<i>Gray v. Sage Telecom, Inc.</i> , No. 3:05-CV-1677-G, 2006 WL 2820075 (N.D. Tex. Oct. 2, 2006)	18
<i>Kennon v. Slipstreamer, Inc.</i> , 794 F.2d 1067 (5 th Cir. 1986)	12
<i>McHann v. Firestone Tire & Rubber Co.</i> , 713 F.2d 161 (5 th Cir. 1983)	12
<i>Merrell Dow Pharm. Inc. v. Havner</i> , 953 S.W.2d 706 (Tex. 1997)	1, 4, 5
<i>Perma Research and Dev. Co. v. Singer Co.</i> , 410 F.2d 572 (2d Cir. 1969)	18
<i>Viterbo v. Dow Chem. Co.</i> , 826 F.2d 420 (5 th Cir. 1987).....	17, 22, 23
<i>Young v. Mem'l Hermann Hosp. Sys.</i> , No. H-03-1859, 2006 WL 1984613 (S.D. Tex. July 14, 2006)	20
FED. R. CIV. P. 56(c).....	23

Plaintiff Failed To Raise A Material Issue Of Fact On Causation

I. Summary of the Argument

The issue before the Court is a simple one: can Plaintiff produce epidemiological evidence, as required by Texas law, to demonstrate an association between her condition and diet drugs? She cannot, because her own experts admit that she does not have the same condition as the patients in the two epidemiological studies on which she relies. The subjects of those studies had elevated pulmonary artery pressures while at rest. Plaintiff concedes she has elevated pulmonary pressures *only on exercise*. That is a distinction with a very important difference. Indeed, if she had tried to join the studies, she would have been refused, because they included only patients who had elevated pulmonary artery pressures *at rest*.¹ And Plaintiff's own experts have conceded that resting PAH and Exercise-Induced PAH have different diagnoses, prognoses, and treatments. Because she cannot show that she is like the patients in the studies, as is required by *Merrell Dow Pharm. Inc. v. Havner*, 953 S.W.2d 706 (Tex. 1997), she cannot rely on the studies she cites to prove causation.

Plaintiff attempts to fit herself within the studies by defining "PAH" broadly to include her condition (i.e. elevated pressures only on exercise), and dismissing the term "Exercise-Induced PPH" as something Wyeth made up. "PAH is PAH," she argues, and therefore the studies apply to her even though she would not have qualified for inclusion in them. This argument does not pass muster under *Havner*. Regardless of how Plaintiff characterizes her condition, it is not the condition that the patients in the studies had. Nor

¹ The studies at issue used the term "PPH." In the briefing on these issues, the parties use the terms "PAH" and "PPH" (Primary Pulmonary Hypertension) interchangeably.

can Plaintiff claim that the condition she has, whatever one calls it, is an “early version” of the condition of the patients in the studies, because her experts expressly concede they do not know if her condition will progress to that condition, and there is no epidemiology suggesting that it will. Resting PAH (the condition in the studies), by contrast to Plaintiff’s condition, is a rapidly progressive and often fatal disease, according to her experts.

Plaintiff’s claim that Wyeth invented the term “Exercise-Induced PPH” is contradicted by her own pleadings and by the testimony of her experts. Her experts over and over again described her condition as “Exercise-Induced PAH,” which they distinguished from resting PAH in terms of diagnosis, prognosis, and treatment. And whether Plaintiff’s condition meets the definition of “PPH” as that term is used in the so-called “Consensus Definition” of PPH agreed to in the MDL settlement agreement (which Plaintiff opted out of) is irrelevant. “PAH” is an umbrella term that includes a number of conditions, two of which are resting PAH and Exercise-Induced PAH. The settlement agreement uses that broad definition as part of a negotiated settlement that Plaintiff rejected. That agreement expressly states that its definition of PAH is *broader* than the definition used in the IPPHS, the primary epidemiological study. *See infra* at 10-11.

In short, the question is not whether Plaintiff meets the “Consensus Definition” or how she labels her condition. The question is: Does she meet the definition of PAH used in the studies on which she relies to prove causation? She does not, by her own experts’ admission. In sum, Plaintiff failed to come forward with adequate epidemiological

evidence to satisfy the substantive state law requirements of *Havner*, which requires reliable epidemiological proof of an association between diet drugs and the condition for which she sues.

Finally, a number of assertions in Plaintiff's response are unsupported by evidence and the Court should disregard them. It also should disregard or strike the portions of her expert's "sham" declaration, in which he changes his sworn testimony without explanation. When Plaintiff's unsupported assertions and sham testimony are disregarded, she is left with no evidence to oppose summary judgment.²

II. Plaintiff Fails to Raise a Material Issue of Fact on Causation

A. There is No Epidemiologic Evidence Showing an Association Between Diet Drugs and Plaintiff's Condition

Plaintiff's experts not only use the term "Exercise-Induced PAH," they acknowledge that no epidemiological studies have been conducted on patients with that condition.³ Plaintiff may now repudiate the term "Exercise-Induced PAH" in an attempt to avoid summary judgment, but her own experts diagnosed her with this condition and their concessions that there is no epidemiology studying it are fatal to her causation claim.

As set forth in Wyeth's Brief at 17, 21, *Havner* requires Plaintiff to prove that she is similar to the test subjects in at least two epidemiological studies whose results indicate

² Plaintiff's Response to Motion for Partial Summary Judgment (Docket # 107) and supporting brief (Docket # 106) is referenced as "Pl.'s Resp." and "Pl.'s Br.," respectively. The Appendix in Support of Wyeth's Motion (Docket # 67:1-3) is referenced as "Wyeth's App." Plaintiff's Appendix (Docket # 94:1-29) is referenced as "Pl.'s App." and Wyeth's Supplemental Appendix is referenced as "Wyeth's Supp. App."

³ See Wyeth's Brief in Support of Motion for Partial Summary Judgment (Docket # 60) ("Wyeth's Br.") at 4-5, 14, 25-29; Declaration of Dr. Harold Palevsky ("Palevsky Decl."), Pl.'s App. at 350-54. The paragraphs in Dr. Palevsky's declaration are unnumbered. For the Court's convenience and to more easily identify the evidence at issue, Wyeth submits in its Supplemental Appendix a copy of the declaration onto which it has marked paragraph numbers. Wyeth's Supp App. 1 at 1. For Dr. Palevsky's acknowledgement or use of the terms "exercise-induced" and "exercise-associated" PAH, see paragraphs 8, 9, 10 (2 times), 11 (2 times), 12 (2 times), 21, 22, 26, and 28.

that it is “statistically more likely than not that [each test subject’s] disease was caused by the drug.” *Havner*, 953 S.W. 2d. at 717; *see also id.* at 714-24. The study results must support an association between the drug and the *specific condition at issue*. *Havner*, 953 S.W.2d at 725.

To raise a fact issue on causation and thus to survive legal sufficiency review, a claimant must do more than . . . show a substantially elevated risk. *A claimant must show that he or she is similar to those in the studies.*

Havner, 953 S.W.2d 720 (emphasis added). Thus, for Plaintiff to rely upon epidemiological studies for proof that diet drugs caused her condition, she must show that she is similar to those in the study, meaning that she has the same medical condition as those studied. She cannot do so here, however, because the only two studies ever done on the association between diet drugs and PAH did not study her condition—they included only those patients who had elevated pressures at rest. In other words, those studies looked only at the connection between diet drugs and resting PAH (PPH), not Exercise-Induced PAH.

Plaintiff claims to have “volumes of scientific studies” that demonstrate diet drugs cause PAH, and that none distinguish between “resting” and “exercise-induced.” (Pl.’s Resp. at 2; Pl.’s Br. at 2). She is wrong. In the less than two pages that she devotes to her causation evidence, she can identify only two studies, the IPPHS⁴ and SNAPH.⁵ These studies looked only at patients with resting PPH (PAH); that is, they defined PPH to *exclude* persons like Plaintiff who had elevated pressures only on exercise. This

⁴ International Primary Pulmonary Hypertension Study (IPPHS), Wyeth’s App. 2 at 13.

⁵ Anorexigens and Pulmonary Hypertension in the United States, Results from the Surveillance of Northern American Pulmonary Hypertension (SNAPH), Pl.’s App. at 369-373.

definition thus was narrower than the “Consensus Definition” for PPH to which Plaintiff cites. (Pl.’s Br. at 10-12).

Studies demonstrating an association between a drug and one condition cannot support a finding of causation with respect to a different condition, even if they are related. *Havner*, 953 S.W.2d at 725; *Exxon Corp. v. Makofski*, 116 S.W.3d 176, 182-85 (Tex. App. – Houston [14th Dist.] 2003, pet. denied) (epidemiological studies showing association between benzene and acute myelogenous leukemia (AML) could not be used to show that benzene cause acute lymphocytic leukemia (ALL)). For this reason, Plaintiff’s half-hearted protest that Wyeth is “re-analyzing” or “dissecting” the studies does not withstand scrutiny. (Pl.’s Resp. at 2; Pl.’s Br. at 12). For purposes of this Motion, Wyeth does not take issue with the conclusions of the IPPHS or SNAPH or reanalyze their findings. Wyeth merely points out that those findings do not apply to Plaintiff’s condition. In short, if Plaintiff does not have PPH *as it was defined in these studies*, she lacks any epidemiological proof, and her claim fails.

1. IPPHS

This study did not include patients with Exercise-Induced PAH; it included only patients who had “the presence of a mean pulmonary artery pressure greater than 25 mm Hg *at rest*.” (Wyeth’s App. 2 at 26) (emphasis added). Plaintiff does not have the condition defined by IPPHS, and she does not have the condition studied in IPPHS. As set forth in Wyeth’s Brief at 6, and as reflected in the IPPHS study protocol (Wyeth’s App. 2 at 20, 26), this epidemiological study included only patients who had elevated resting pulmonary artery pressures, which Plaintiff concedes she does not have.

(Wyeth's Br. at 6-12). Thus, this study cannot support an association between diet drugs and her condition.

2. SNAPH

Assuming that this study qualifies as a valid epidemiological study under *Havner*, it does not support causation for Plaintiff either.⁶ The study included only patients with resting elevated pressures: "Pulmonary hypertension was defined [for the study] as mean pulmonary artery pressure, measured at cardiac catheterization, that was > 25 mm Hg . . ."⁷ This is the well-settled definition of elevated resting pulmonary artery pressures.⁸ Plaintiff does not have PPH defined by SNAPH, and she does not have the condition that was studied in SNAPH. Therefore, even if SNAPH provides epidemiological support for an association between diet drugs and resting pulmonary hypertension, its conclusions do not apply to Plaintiff because she does not have that condition. (*See* Wyeth's Br. at 17, 21).

B. Plaintiff Claims Exercise-Induced PAH

For the first time in over eight years since she filed suit, Plaintiff makes the astonishing statement that she does not claim "Exercise-Induced" PAH, that this is just "Wyeth's term" for her condition. (Pl.'s Resp. at 1; Pl.'s Br. at 1). But this so-called "artificial distinction" between Exercise-Induced and resting PAH, which she calls a "deliberate misnomer," is Plaintiff's experts' distinction, and it is a legitimate one. Plaintiff and her experts make this same distinction over and over, in her expert

⁶ Because the MDL court referred to SNAPH as a "well done epidemiological study," Wyeth will assume without conceding that it provides valid epidemiological data, without analyzing any deficiencies that might exist under *Havner*, a state standard that is more rigorous than that in some jurisdictions.

⁷ Study at 871; Pl.'s App. at 370.

⁸ Declaration of Dr. Steven Koenig ¶ 7, Wyeth's Supp. App. 2 at 7.

designations and her experts' reports and depositions — that she has Exercise-Induced PAH in contrast to resting PAH.⁹ Dr. Palevsky continues to refer to her condition as “Exercise-Induced” or “Exercise-Associated” PAH in his declaration offered in opposition to summary judgment.¹⁰ Moreover, in her response to Wyeth's motion to limit prognosis-related testimony about the progressive PPH condition, she admits the distinction: “It is well established that PAH is a progressive disease that can lead to death by heart failure. [citation omitted] However, it is not well established whether Cindy Burton's PAH will progress or worsen in the future.”¹¹

1. Dr. Poon

Dr. Michael Poon, Plaintiff's treating physician who first diagnosed her with elevated pulmonary artery pressures, testified that she had “mild *exercise-induced* pulmonary hypertension,” and “*exercise-induced* pulmonary hypertension.”¹² Dr. Poon distinguished “exercise-induced” pulmonary hypertension from resting (fixed) pulmonary hypertension: “*exercise-induced* probably is significantly better [than resting] in terms of prognosis.”¹³ Dr. Poon twice *corrected* Plaintiff's counsel when he omitted the term “exercise-induced”:

- Q. Am I correct that . . . you diagnosed Ms. Burton with pulmonary arterial hypertension, correct?
[objection omitted]
- A. *Exercise-induced.*

⁹ Expert Witness Disclosures of Plaintiff Cynthia Ann Burton, October 13, 2006, p. 4; Wyeth's Supp. App. 3 at 48; Expert Report of Dr. Harold Palevsky, October 16, 2006, at 5-6; Wyeth's Supp. App. 4 at 53-54.

¹⁰ Palevsky Decl. ¶ 11; Wyeth's Supp. App. 1 at 2.

¹¹ Plaintiff's Brief In Response to Wyeth's Motion to Exclude Plaintiff's Expert Testimony Regarding Pulmonary Hypertension Medical Prognosis (Docket # 107) (“Pl.'s Prognosis Br.”) at 2 (emphasis added).

¹² Wyeth's Br. at 11-12; Deposition of Dr. Poon, at 112:22-113:5; 117:5-9; Wyeth's Supp. App. 5 at 61-62 (emphasis added).

¹³ *Id.* at p. 120:15-18; Wyeth's Supp. App. 5 at 64 (emphasis added).

Q. I stand corrected. She had *exercise-induced* pulmonary arterial hypertension?

A. Right.

...

Q. So you diagnosed her with pulmonary arterial hypertension?

A. Correct, *exercise-induced*.¹⁴

2. Dr. Palevsky

In her Expert Witness Disclosures of October 16, 2006, Plaintiff stated that her retained expert pulmonologist, Dr. Palevsky, would testify that “Ms. Burton has *exercise-induced* pulmonary arterial hypertension.”¹⁵ In Dr. Palevsky’s expert report, Dr. Palevsky repeated this diagnosis several times: (1) “Plaintiff’s cardiac catheterizations “are diagnostic of *exercise-induced* pulmonary arterial hypertension;”¹⁶ (2) “Ms. Burton’s *exercise-associated* pulmonary arterial hypertension ...”¹⁷; (3) “[her] prognosis of *exercise-associated* pulmonary arterial hypertension is incompletely understood.”¹⁸ In his subsequent deposition, Dr. Palevsky reiterated this precise diagnosis:

Q. With respect to Cindy Burton, I understand from your report that you have diagnosed her with, I think you phrased it “*exercise-associated* pulmonary arterial hypertension.”

A. Yes.¹⁹

He repeatedly distinguished her condition from resting or “fixed” PAH,²⁰ and referenced her “*exercise-associated* pulmonary hypertension.”²¹ In fact, no fewer than *forty-one times* in his deposition he used the term “exercise-induced” or “exercise-associated,” or

¹⁴ *Id.* pp. 124:10-18; 125:22-24; Wyeth’s Supp. App. 5 at 65, 66 (emphasis added).

¹⁵ Plaintiff’s Expert Witness Disclosures at p. 4; Wyeth’s Supp. App. 3 at 48. (emphasis added).

¹⁶ Palevsky Expert Report at p. 5; Wyeth’s Supp. App. 4 at 53.

¹⁷ *Id.* at p. 6.

¹⁸ *Id.*

¹⁹ Deposition of Dr. Palevsky p. 18:13-18; Wyeth’s App. 4 at 48 (emphasis added).

²⁰ *Id.* at p. 105:8-10; Wyeth’s App. 4 at 53.

²¹ *Id.* at p. 136:15-18; Wyeth’s Supp. App. 6 at 83 (emphasis added).

responded to questions about it.²² Dr. Palevsky's own abstract discussed in Wyeth's Brief made the distinction of "Exercise-Associated" PH. (See Wyeth's Br. at 27-28).

3. Dr. Channick

Similarly, Plaintiff's expert Dr. Channick embraced the term, referring to his own and others' case reports about patients with "Exercise-Induced" PAH,²³ to patients with "Exercise-Induced" pulmonary hypertension,²⁴ and to Plaintiff's Exercise-Induced PAH.²⁵ In 2006, Dr. Channick confirmed Plaintiff's diagnosis of "*Exercise-Induced* PAH."²⁶ Dr. Channick himself studied patients with *Exercise-Induced* PAH: he prepared a case report on patients with *Exercise-Induced* PAH, in which he concluded that 70% of those with *Exercise-Induced* PAH do not progress or deteriorate.²⁷

Plaintiff's experts recognize the distinctions in the epidemiological studies — and concede that no epidemiological studies have been conducted on patients with exercise-induced PAH. Nor have treatment drugs been studied in this group, because, they concede, the studies and treatments have been done only for those with *resting* PAH.²⁸ Dr. Palevsky admits this even in his declaration offered in opposition to summary judgment.²⁹

²² See Palevsky Deposition at 12:20; 18:16,20; 34:5; 62:22; 84:18; 86:23; 91:13; 101:13; 103:5, 24; 104:21; 105:21; 106:5; 108:7,20; 111:20,25; 120:8; 121:10; 124:6; 127:20; 131:7,15; 133:16; 134:10; 135:5,10; 136:7,13,18,20; 137:8,10,22,25; 138:2,16,23; 139:3,20; 139:3, 16,23; 144:13; Wyeth's App. 4 at 48, 52-54, 56, 64-66, 68 and Wyeth's Supp. App. 6 at 70-87.

²³ Deposition of Dr. Richard Channick, April 5, 2005, at 139:3-13; 141:3-12; Wyeth's App. 5 at 77, 78.

²⁴ *Id.* at 142:1-12, 16-20; 144:19-23; 148:15-18; 149:4-7; 155:12-18; 157:21-158:2; 159:14-18; 161:18-22; 163:6-12, 15-17; Pl.'s App. at 607, 609, 611, 613, 615, 621, 623, 625, 627.

²⁵ *Id.* at 150:22-151:2; Pl.'s App. at 615, 617.

²⁶ Deposition of Dr. Richard Channick, Nov. 1, 2006, 174:25-175:5, Wyeth's App. 6 at 86-7.

²⁷ Deposition of Dr. Richard Channick, April 5, 2005, at 143:6-9; 146:10-20; 148:20-23; Wyeth's App. 5 at 80-82; Deposition of Dr. Richard Channick, November 1, 2006, at 234:18-24; Wyeth's App. 6 at 92.

²⁸ See Wyeth's Br. at 4-5, 14, 25-29; Palevsky Decl. ¶ 11; Wyeth's Supp. App. 1 at 2.

²⁹ Palevsky Decl. ¶ 11; Wyeth's Supp. App. 1 at 2.

In light of this evidence, it is disingenuous at best for Plaintiff now to claim that Wyeth made up the term “Exercise-Induced PAH.” In doing so, she hopes to blur the distinction her own experts have made between this condition (which she has), and the progressive, resting PAH (which she does not have), so she can argue that the studies showing an association between diet drugs and the latter condition also support causation for her condition. This is a distortion of the facts to avoid summary judgment on causation.

C. The “Consensus Definition” of PPH Does not Supply Causation Evidence

Plaintiff argues 1) there is a “Consensus Definition” of PPH (PAH) that includes elevated pressures on exercise; 2) Wyeth entered into a Settlement Agreement that included the “Consensus Definition” of PPH; 3) the diet drug MDL court accepted the “Consensus Definition,” and 4) experts on both sides of this case have used the “Consensus Definition.” She reasons that because she fits within the “Consensus Definition” of PPH (PAH), the studies that show an association between diet drugs and resting PPH establish causation for her, too.

The flaw in this argument is simple: the “Consensus Definition” is broader than the definition of PPH studied in the epidemiological studies. The fact that some in the medical community accept this broader definition of PPH as a general proposition, however, does not obviate the requirement of epidemiological studies to establish causation under *Havner*.

1. The Settlement Agreement

a. The Settlement Definition Expressly was Broader Than the Studies

In 1999, Wyeth entered into a Nationwide Class Action Settlement Agreement (“Settlement Agreement”) that preserved the right to sue for those who met the Settlement Agreement’s definition of PPH.³⁰ The agreement defined PPH as including a pulmonary artery pressure reading of “... \geq 30 mm Hg with exercise . . .” (Pl.’s App. at 656), which the MDL court termed the “Consensus Definition” for PPH. Misleadingly, however, Plaintiff omits other key language in the Settlement Agreement, which explicitly provides that the settlement definition is *broader* than the definition of PPH in the IPPHS study:

This definition of PPH (“the PPH Definition”) is intended solely for the purpose of describing claims excluded from the definition of [claims settled under the agreement.] *The Parties agree that the PPH Definition includes but is broader than the rare and serious medical condition suffered by individuals described in [the IPPHS study.] . . . While the IPPHS subjects would fall within the PPH Definition, the definition also includes persons with a milder, less serious medical condition.*

Wyeth’s Supp. App. 7 at 92) (emphasis added).

In other words, the entire settlement relating to PPH, and the MDL court’s subsequent review of this issue, turned on a definition of PPH that was *broader than that used in the epidemiologic studies*. Moreover, the Settlement Agreement merely allowed those who remained in the class to sue for “PPH” defined in the agreement — it did not establish their right to recover or provide evidence for them of the necessary element of causation. (Pl.’s App. at 71). And the Settlement Agreement includes an explicit statement in its Preamble that “[it] shall not be construed as evidence of or as an

³⁰ Wyeth formerly was known as American Home Products Corp. The MDL court approved the Settlement Agreement in *Brown v. Am. Home Prods. Corp., In re: Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig.*, 2000 WL 1222042 (E.D. Pa. Aug. 28, 2000) (PTO 1415); Pl.’s App. at 1-155.

admission by [Wyeth] of any liability . . .” (Wyeth’s Supp. App. 7 at 90). Given the language cited above, Plaintiff’s attempt to turn the settlement definition into an admission by Wyeth can only be viewed as an attempt to mislead the Court. And use of the settlement as a purported admission also runs afoul of Fed. R. Evid. 408. *See Branch v. Fid. & Cas. Co. of New York*, 783 F.2d 1289, 1294 (5th Cir. 1986) (settlement evidence not admissible on liability and damages); *Kennon v. Slipstreamer, Inc.*, 794 F.2d 1067, 1071 (5th Cir. 1986) (“The central purpose of Rule 408 is to exclude compromise negotiations as to all rights they do not expressly control”). *McHann v. Firestone Tire & Rubber Co.*, 713 F.2d 161, 166 (5th Cir. 1983) (“[N]or can plaintiff show the defendant's liability or extent of liability, by proof of defendant's settlement with a third person.”).

b. Plaintiff Rejected Any Benefits of the Broader Settlement Agreement Definition

To the extent that the definition of PPH in the Settlement Agreement includes a condition broader than the PPH definition of the IPPHS, Plaintiff has waived any right to invoke its benefit in this case. The benefits of the Settlement Agreement accrued only to those who did not opt-out from them. (Pl.’s App. at 58-59). By opting out, Plaintiff expressly rejected any benefits of the Settlement Agreement in March 2000, when she opted-out of that broader definition:

“... I HEREBY KNOWINGLY AND PERMANENTLY RELINQUISH, WAIVE AND GIVE UP ALL OF THE RIGHTS WHICH I WOULD OTHERWISE HAVE AS A CLASS MEMBER UNDER THE SETTLEMENT AGREEMENT . . . AND FOREVER OPT-OUT OF THE CLASS WITH FULL KNOWLEDGE OF THE LEGAL, FACTUAL AND MEDICAL CONSEQUENCES OF MY ACTION.”

(Cindy Burton’s “Initial Opt-Out Form”; Wyeth’s Supp. App. 8 at 95).

2. The Diet Drug MDL Court's Actions Are Not Evidence of Causation

Plaintiff argues that the diet drug MDL court's acceptance of the "Consensus Definition" for PPH in approving the Settlement Agreement means she has "PPH" as defined in the epidemiological studies on which she relies. She is wrong for three reasons.

First, the MDL Court was approving a settlement of disputed claims. In PTO 1415,³¹ the court reviewed and approved the settlement at the request of the parties, based on the evidence offered at the settlement approval hearing. The parties agreed on the broader "Consensus Definition" in compromise of litigation. While the definition was supported by evidence at the settlement hearing, it was done in the context of this settlement, and therefore neither the definition nor the court's approval of it constitutes evidence for causation here.

Second, when the MDL judge wrote that "well done epidemiological studies establish that the use of [diet drugs] cause PPH" (Pl.'s Br. at 7), he referenced the IPPHS and SNAPHS—both of which excluded Exercise-induced PAH from the definition of PPH. (*See supra* Sec. II.A). Moreover, Judge Bechtel was contemplating *resting* PPH: "PPH is a relentlessly progressive disease that leads to death in virtually all circumstances....[I]t is a virtual death sentence." (Pl.'s App. at 39). Plaintiff concedes she does not have this condition.

Finally, Plaintiff cannot use statements of a court in approving a settlement agreement as a substitute for the epidemiological evidence that Texas law requires; instead, she must come forward with evidence that shows an association between diet

³¹ *See supra* fn. 30; Pl.'s App. at 1.

drugs and her condition. Wyeth does not ask the Court to rule in a manner inconsistent with the MDL court or to disregard the language in PTO 1415; rather, it asks the Court to hold Plaintiff to her burden under *Havner* to come forward with proper summary judgment evidence of causation. She cannot supply this critical element of her case by reference to a court order approving a settlement agreement.

3. Plaintiff's Misstatements and Inflammatory, Irrelevant Accusations Are Not Evidence of Causation

a. Defense Experts Dispute Causation

In an effort to support her claim that she has PAH linked to diet drugs, Plaintiff cites to defense depositions and expert reports, asserting that 1) the defense concedes she has PAH; 2) PAH is caused by diet drugs; 3) therefore the defense concedes her PAH is caused by diet drugs. But Wyeth's experts always have distinguished resting from Exercise-Induced PAH. That they cite to the current "Consensus Definition" of PAH, does not supply proof of causation for a condition never studied in the only epidemiological studies ever done. Plaintiff states that defense expert Dr. Steven Koenig acknowledges she has "pulmonary hypertension," agreeing that it would be "wrong to state that she does not". (Pl.'s Br. at 9; citing Pl.'s App. at 465). But Plaintiff omitted his testimony that Plaintiff has only *Exercise-Induced* pulmonary hypertension:

Q. ...Does Cynthia Burton have pulmonary hypertension of some kind?

A. *Exercise-induced* pulmonary hypertension.³²

Next, she cites selective portions of deposition testimony, quoting Dr. Koenig's statement that he had seen patients with pulmonary hypertension caused by diet drugs,

³² Koenig Deposition at 100:19-22; Pl.'s App. at 465 (emphasis added).

thus implying that Wyeth's own expert admits that diet drugs cause Plaintiff's condition.³³ But Plaintiff omits that upon further questioning, Dr. Koenig testified that these were patients with only elevated *resting* pressures: "[B]efore I will attribute someone's pulmonary hypertension to diet drugs, based on the literature, ... *they also have to have resting pulmonary hypertension.*"³⁴

Plaintiff next cites to the expert reports of Drs. Koenig and Champion to argue that because Wyeth's experts acknowledge the "Consensus Definition" of PPH (PAH) that includes exercise, Wyeth has conceded causation. (Pl.'s Br. at 10-11). Not true. The issue before the Court is not what a definition says or whether it is accepted in some other context; the issue is whether Plaintiff can use that definition, standing alone, to meet her burden on causation — which requires epidemiological studies — *when the studies did not use this broad a definition for PPH*. Wyeth submits that the "Consensus Definition," standing alone, is insufficient as proof of causation. *Havner* does not allow her to bootstrap onto the studies' findings when the studies did not use the "Consensus Definition" for PPH and when patients with her condition were not included in the studies. Whatever the diagnostic criteria and "Consensus Definition" may mean, they are not epidemiologic studies, nor can they substitute for them under *Havner*.

b. "No Literature"

Plaintiff asserts that there is no scientific literature to support the distinction between resting and Exercise-Induced PAH, claiming it is an "artificial construct." (Pl.'s Br. at 11 n.13). She implies that Wyeth has the burden to produce scientific literature

³³ *Id.* at 46:6-10; Pl.'s App. at 415-16; Pl.'s Br. at 8.

³⁴ *Id.* at 100:6-12; (emphasis added); Pl.'s Br. at 8; Pl.'s App. at 464.

distinguishing the conditions. This argument stands *Havner* on its head — it is *her* burden to produce epidemiological literature supporting her claim that diet drugs caused *her* condition.³⁵ Given Plaintiff’s own distinctions and those of her experts set out above, it is difficult to see how she can maintain this position. And the whole point of this motion is that the Exercise-Induced PAH condition has never been the subject of epidemiological studies, so of course there is no epidemiology on it. But case reports and abstracts, not themselves adequate to prove causation, have made the distinction. For example, Plaintiff’s expert Dr. Channick discussed an unpublished case study he authored in which he made precisely that distinction, finding that 70% of exercise PAH patients did not progress.³⁶ And Dr. Palesvsky authored a case-study abstract that included “Exercise-Associated Pulmonary Hypertension” in its title. (See Wyeth’s Br. at 27-8; Wyeth App. 13 at 128). The writings and testimony of Plaintiff’s own experts belie her argument that medical literature (limited as it is on her condition) makes no distinction between patients with resting and Exercise-Induced PAH. In short, there are only two studies that address *any* association between diet drugs and PAH, and neither one considered Exercise-Induced PAH. There are *no* studies demonstrating an association between diet drugs and Exercise-Induced PAH.

c. Conclusory Opinion

Citing a classic ‘*ipse dixit*’ of her experts, Plaintiff quotes Dr. Channick’s pronouncement that there is “ample epidemiological evidence” that diet drugs increase the risk of pulmonary hypertension, which definition Plaintiff meets. (Pl.’s Br. at 13).

³⁵ See Wyeth’s Br. at 17, 21.

³⁶ Deposition of Dr. Channick, April 5, 2005, at 141:3-143:9, Wyeth’s App. 5 at 78-80.

But he cites to none, and Plaintiff has only come forward with the IPPHS and SNAPH studies, neither of which provide an association for Plaintiff's condition. Under *Havner*, Plaintiff must produce epidemiological evidence, not bare conclusions of causation by her experts. Dr. Channick's bare conclusion, unsubstantiated by any epidemiological evidence, is insufficient to raise a fact issue on causation. *Clark v. America's Favorite Chicken Co.*, 110 F.3d 295, 297 (5th Cir. 1997) ("affidavit or deposition testimony setting forth ultimate or conclusory facts . . . are insufficient to defeat motion for summary judgment"). Federal courts recognize that it is not so simply because "an expert says it is so." *Viterbo v. Dow Chem. Co.*, 826 F.2d 420, 421 (5th Cir. 1987). The Court should disregard this unsubstantiated opinion.

d. Injection of Liability Arguments

Presumably in an effort to bias the Court and divert attention from her weak causation case, Plaintiff devotes three pages in her brief to her liability allegations against Wyeth in exceedingly inflammatory and prejudicial language. (Pl.'s Br. at 4-7). Wyeth adamantly denies the allegations and the characterization of both its conduct and the hodge-podge of documents she appends, but these matters are not in issue now. All of this is irrelevant to the medical causation issues before the Court and should be disregarded.

D. Dr. Palevsky's "Sham" Declaration And Conclusory Assertions Should Be Disregarded or Stricken

In opposition to Wyeth's Motion, Plaintiff submits a declaration of her expert Dr. Palevsky,³⁷ in which he makes assertions that directly and materially contradict his

³⁷ See Wyeth's Supp. App. 1 at 1; Pl.'s App. at 350-354, "Palevsky Decl."

December, 2006 sworn deposition testimony, without explanation. These contradictions should be disregarded or stricken. A party may not defeat a motion for summary judgment by using an affidavit that, without explanation, impeaches his prior testimony. *Doe v. Dallas Indep. Sch. Dist.*, 220 F.3d 380, 386 (5th Cir. 2000) (“If a party who has been examined at length on deposition could raise an issue of fact simply by submitting an affidavit contradicting his own prior testimony, this would greatly diminish the utility of summary judgment as a procedure for screening out sham issues of fact.” (quoting *Perma Research and Dev. Co. v. Singer Co.*, 410 F.2d 572, 578 (2d Cir. 1969))); *Campanello v. Anthony & Sylvan Pools Corp.*, No. Civ. A. 3:03-CV-1884-G, 2004 WL 2049313, at *5 (N.D. Tex. Sept. 14, 2004) (to the extent that affidavit contradicts prior deposition testimony, court will disregard it). Plaintiff cannot create a genuine issue of material fact simply by proffering her expert’s declaration that conflicts with his prior sworn testimony. *Copeland v. Wasserstein, Perella & Co., Inc.*, 278 F.3d 472, 482 (5th Cir. 2002). Because certain paragraphs in Dr. Palevsky’s declaration impeach his prior sworn testimony without explanation, this Court should disregard or strike them.

The Court also should disregard Dr. Palevsky’s conclusory, unsubstantiated assertions. “Statements setting forth conclusory or ultimate facts or asserting conclusions of law are insufficient evidence on a motion for summary judgment.” *Gray v. Sage Telecom, Inc.*, No. 3:05-CV-1677-G, 2006 WL 2820075, at *5 (N.D. Tex. Oct. 2, 2006) (citing *Clark*, 110 F.3d at 297).

1. Dr. Palevsky’s Contradictory Testimony

a. Progression Of Exercise-Induced Pulmonary Hypertension

In Paragraphs 8-11, Dr. Palevsky states, without citation of authority, that measurements of elevated pressures on exercise are the “earliest point” that doctors can document the development of pulmonary vascular injury (§ 8), that structural changes to the pulmonary artery bed are progressive (§§ 9-10), culminating in his ultimate conclusion: “The progression of ‘normal’ to exercise-associated pulmonary hypertension and then to resting pulmonary hypertension and the development of right heart failure is the progression that every patient with pulmonary hypertension goes through.” (§ 11). In Paragraph 28, Dr. Palevsky states: “Experience and studies of patients with pulmonary arterial hypertension indicate that the *majority of patients either progress. . .*” and concludes “I believe that Ms. Burton’s PPH will more likely than not remain the same *or progress in the future.*” (emphasis added).

Dr. Palevsky’s new conclusion that Exercise-Induced PAH is progressive directly contradicts both his sworn testimony and Plaintiff’s admissions. In another brief, Plaintiff conceded:

It is well established that PAH is a progressive disease that can lead to death by heart failure [citation omitted]. *However, it is not well established whether Cindy Burton’s PAH will progress or worsen in the future.*

(Pl.’s Prognosis Br. at 2) (emphasis added). She also concedes that she will not offer evidence at trial that her condition is progressive or that it will worsen, admitting that “the future is unknown.” (*Id.* at 1, 2).

Her experts supported this position *before Wyeth filed its summary judgment motion.*³⁸ At his deposition just two months ago, Dr. Palevsky testified unequivocally

³⁸ See Wyeth’s Br. at 12-14; Wyeth’s Brief in Support of Motion to Exclude Plaintiff’s Expert Testimony Regarding Pulmonary Hypertension Medical Prognosis at 5-13 (Docket # 53).

that he *cannot predict Plaintiff's prognosis* and that *there is no medical literature to help him predict it.*³⁹ He admitted that there was “no way” to predict her course with exercise

PAH:

- Q. If we look at a prognosis for the future . . . is there any published data which is going to help you predict for Ms. Burton what is likely to happen?
- A. So, no. . . . [T]here's no way to predict likelihood of remaining stable versus likelihood of progressing over the next five years.
- . . .
- Q. Is there any way to state to a reasonable degree of medical certainty that she will need [certain medications for progressive PAH] or interventions such as that?
- A. No. Those are possibilities, what we would use if there was progression, but there's — if there's no way to predict stability, there's no way to predict progression.⁴⁰

He could not say to a reasonable degree of medical probability that she would progress to a state of resting pulmonary hypertension:

- Q. In your report, you say that, “The prognosis of exercise-associated pulmonary arterial hypertension is incompletely understood at this point in time.” Is that correct?
- A. You read that well.
- Q. All right. Can you say to a reasonable degree of medical certainty that she will progress to a state of resting pulmonary arterial hypertension?
- A. No . . . we would hope she will not be progressing to fixed pulmonary hypertension.⁴¹

His contrary statements in his declaration that the Exercise-Induced condition can progress, or that Plaintiff's condition will progress, should be stricken or disregarded.

See Young v. Mem'l Hermann Hosp. Sys., No. H-03-1859, 2006 WL 1984613, at *3-5

(S.D. Tex. July 14, 2006) (court disregarded affidavits of medical experts that plaintiff's

³⁹ Deposition of Dr. Harold Palevsky, Dec. 15, 2006, at 131:3-132:1; Wyeth's App. 6 at 66-67.

⁴⁰ *Id.* at 131:3-132:1; 133:3-12; Wyeth's App. 6 at 66-68.

⁴¹ *Id.* at 104:20-105:10; Wyeth's App. 4 at 52-53.

would have had a 51% or greater chance of avoiding severely disabled condition if he had received particular treatment where affidavits contradicted prior deposition testimony).

b. Causation

In Paragraph 12 of his declaration, Dr. Palevsky offers a conclusory statement that Exercise-Induced PAH is caused by the same process as resting PAH, which he then states in Paragraph 12 is caused by diet drugs: “The same processes that have been *well documented* as causing resting pulmonary hypertension (and resting pulmonary arterial hypertension) cause exercise-associated pulmonary arterial hypertension.” (emphasis added). Dr. Palevsky concludes: “Ms. Burton’s exercise associated PAH was, within a reasonable degree of medical certainty, caused by fenfluramines.” (*Id.* at ¶ 26).

These conclusory statements setting forth ultimate facts are insufficient summary judgment evidence. *See Clark*, 110 F.3d. at 297. Moreover, he contradicts his prior testimony that no studies support causation. Dr. Palevsky admitted in his deposition, as have all of Plaintiff’s experts, that there are no epidemiological studies that show that Exercise-Induced, as opposed to resting PAH, is caused by diet drugs. (*See supra*, Sec. IIB; *see also* Wyeth’s Br. at 25-29). Moreover, in the same declaration in which Dr. Palevsky concludes that diet drugs cause Exercise-Induced PAH, he concedes in another paragraph *that the exercise condition has not been studied*: “[t]he fact that epidemiologic studies such as the IPPHS and the treatment trials leading to the development of the current therapies for pulmonary arterial hypertension *have focused on patients with*

resting pulmonary hypertension is based on [two reasons.]”⁴² Thus, while attempting to explain *why* Exercise-Induced PAH has not been studied, Dr. Palevsky concedes the premise of Wyeth’s motion — that this condition has not been the subject of epidemiologic studies. The contradictory and unsupported assertions of causation in Paragraphs 9-11 and 28 should be stricken or disregarded.

2. Conclusory Statements on Causation

In Paragraphs 16 and 18, in an effort to support his opinion that diet drugs caused Plaintiff’s exercise condition, Dr. Palevsky references “other studies” (¶ 16) and the opinions of “the scientific community” that diet drugs cause PPH (presumably implying that they caused Plaintiff’s condition, too). (¶ 18). These references have no evidentiary support other than the expert’s bare “say-so” and should be disregarded as conclusory. *See Viterbo*, 826 F.2d at 421. Surely if Plaintiff and her experts had “other studies” or “volumes of studies” that establish causation for her condition by valid epidemiology, (Pl.’s Br. 2), her experts would have identified them in depositions or she would supply them in her opposition to summary judgment. But she references only two studies, and neither defined PPH to include Plaintiff’s condition or studied Plaintiff’s condition. Thus, these two conclusory statements should be disregarded or stricken.

Finally, Dr. Palevsky concludes that “Ms. Burton’s exercise-associated PAH, was, within a reasonable degree of medical certainty, caused by fenfluramines [diet drugs].” Palevsky Decl. at ¶ 26). This ultimate opinion on causation is wholly conclusory, and therefore insufficient summary judgment evidence. *Clark*, 110 F.3d at 297 (statements

⁴² Palevsky Decl. ¶ 11; Wyeth’s Supp. App. 1 at 2 (emphasis added).

setting forth conclusory or ultimate facts are insufficient summary judgment evidence).

It is not so just because Dr. Palevsky says it is so. *See Viterbo*, 826 F.2d at 421.

Plaintiff's inability to provide a valid scientific basis for this opinion is fatal to her causation claim, and this conclusory statement cannot revive it.

F. Plaintiff's Unsupported Arguments Are Not Summary Judgment Evidence

Statements in Plaintiff's Brief, unsupported by valid summary judgment evidence, are unsubstantiated assertions, which are not competent summary judgment evidence.

See Fed. R. Civ. P. 56(c); *Calbillo v. Cavender Oldsmobile, Inc.*, 288 F.3d 721, 725 (5th Cir. 2002).

The following unsubstantiated assertions in Plaintiff's Brief, therefore, should be disregarded:

- “[T]he distinction of “exercise-induced” by Wyeth as some other disease process is flatly wrong and not accepted or recognized by the medical or scientific community.” (Pl.’s Br. at 1-2).
- “[V]olumes of scientific studies” or “voluminous factual and epidemiological evidence” demonstrate that Wyeth’s diet drugs cause PAH. (*Id.* at 2, 4).
- “The medical literature *never* suggests a diagnosis of PAH with exercise is somehow a different disease process”. (*Id.* at 4) (emphasis in original).
- “[E]xercise induced’ PAH (Wyeth’s term) is the *same disease* as resting PAH.” (*Id.* at 4) (emphasis in original).
- “There is voluminous factual and epidemiological evidence that PAH is caused by Wyeth’s diet drugs.” (*Id.* at 4).
- “[T]he medical and scientific community universally recognizes that PAH diagnosed on ‘exercise’ is just as much PAH as resting PAH.” (*Id.* at 9).
- “Cindy Burton’s ‘exercise-diagnosed’ PAH is just as much PAH as ‘resting diagnosed’ PAH.” (*Id.* at 11).

Each of these assertions in Plaintiff’s brief is unsupported by any competent summary judgment evidence, and therefore should be disregarded.

Conclusion

The issue is straightforward under *Havner*. To raise a fact issue on causation Plaintiff must provide at least two epidemiological studies that demonstrate a statistically significant association between diet drug and *her condition*. It is uncontroverted that IPPHS and SNAPH did not study subjects like her. Under Texas law, she cannot prove causation and the Court should grant summary judgment for Wyeth on Plaintiff's PAH claim.

Respectfully submitted,

s/ Leslie A. Benitez

Kenneth J. Ferguson
State Bar No. 06918100
kjf@ctw.com
Leslie A. Benitez
State Bar No. 02134300
lab@ctw.com
David S. Lill
State Bar No. 12352500
dsl@ctw.com
David J. Duke
State Bar No. 00795983
djd@ctw.com

CLARK, THOMAS & WINTERS, P.C.

P.O. Box 1148
Austin, Texas 78767
(512) 472-8800 (Telephone)
(512) 474-1129 (Facsimile)

And

Grant Liser
State Bar No. 12415000
gliser@browndean.com

**BROWN, DEAN, WISEMAN, LISER,
PROCTOR & HART, L.L.P.**

306 W. 7th Street
Fort Worth Club Building
Suite 200

Ft. Worth, Texas 76102
(817) 332-1391 (Telephone)
(817) 870-2427 (Facsimile)

ATTORNEYS FOR DEFENDANT WYETH

CERTIFICATE OF SERVICE

By my signature below, I hereby certify that a true and correct copy of the foregoing was served on counsel of record via electronic filing or certified mail on this the 26th day of February, 2007:

Via ECF

David W. Holman
The Holman Law Firm, P.C.
24 Greenway Plaza, Suite 2000
Houston, Texas 77046
713/400-4841 – Fax

John Kopesky
Sheller, Ludwig & Badey
1528 Walnut Street, 3rd Floor
Philadelphia, PA 19102
215/546-0942 – Fax

Mary Alice McLarty
The McLarty Firm, P.C.
3811 Turtle Creek Blvd., Suite 1400
Dallas, Texas 75219
972/774-9889 - Fax

Via Certified Mail

Raymond Valori
Law Office of Raymond Valori
2665 Executive Park Dr., Suite 3
Weston, Florida 33331
954/670-2530
Counsel for Plaintiff

Via ECF

David P. Stone
Hartline, Dacus, Barger, Dryer & Kern
6688 N. Central Expwy, Suite 1000
Dallas, Texas 75206
214/369-2118 - Fax
Counsel for Eckerd Drugs

_____/s/ Leslie A. Benitez